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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,742	10/22/2003	Kenneth Jacobs	00766.000091.10	8823

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/689,742	KENNETH JACOBS	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *192,194,195 and 198-201* is/are pending in the application.

4a) Of the above claim(s) *198-201* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *192,194 and 195* is/are rejected.

7)☒ Claim(s) *192,194 and 195* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/22/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Applicants' preliminary amendment filed on October 22, 2003 is acknowledged. Claims 1-191, 193, 196, 197 and 202-269 have been canceled. Therefore claims 192, 194, 195 and 198-201 are currently pending and are under consideration.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 192, 194 and 195, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 159, that encodes a protein set forth in SEQ ID NO: 160, an isolated gene with cDNA sequence set forth in clone bn97_1, vector, host cell: classified in class 435, subclass 69.1, class 536, subclass 23.1, 23.5.

Group II. Claims 198-201, drawn to an isolated protein comprising or related to SEQ ID NO: 160 and fragments thereof, wherein said amino acid sequence is encoded by the cDNA insert of clone bn97_1, wherein said protein comprises the amino acid sequence of SEQ ID NO: 2, a composition comprising the protein related to SEQ ID NO: 160; classified in class 530, subclass 350.

Should group II be elected, Applicants are required to select one sequence SEQ ID NO: 160 from claim 198 or SEQ ID NO: 2 from claims 199 and 200. Because the polypeptides have sequences that are structurally different, are considered patentably distinct, **this is not a species election.**

The inventions are distinct, each from the other because of the following reasons:

Inventions in Group I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP ' 806.04, MPEP ' 808.01). In the instant case the polynucleotide of Group I and polypeptide of Group II differ with respect to their structure, and their physical, chemical and biological properties and function. The polynucleotides of Group I can be used for hybridization assay while the polypeptides of Group II can be used to make antibodies. Therefore, the inventions are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Attorney John Magluyan on September 30, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 192, 194 and 195. Affirmation of this election must be made by applicant in replying to this Office action. Claims 198-201 withdrawn from further consideration by the examiner, as being drawn to a non-elected invention (37 CFR 1.142(b)). Therefore, claims 192, 194 and 195 are currently pending and are under examination.

Priority

Applicants' claim for domestic priority under 35 U.S.C. 119(e) and 120 is acknowledged. Applicant is requested to update the status of the documents to reflect their current status. As the list of related files is fairly long, and computer readable formats of the sequence listings for the

applications are not all available, Applicants are required to specifically disclose which priority applications disclose the elected sequences SEQ ID NOs: 159 and 160, and to state where in those applications the disclosure is located by page and line number. For the current prosecution, the parent application 09/746783 filed on December 21, 2000 is considered for the priority date applied in the instant application.

Objection to the Specification

The disclosure is objected to for the following informalities:

The abstract of the disclosure is objected to because the abstract is not descriptive of the claimed invention. Appropriate correction is required. See MPEP § 608.01(b).

The specification is objected to because the continuing data needs to be updated.

Objection to the claims

Claims 192, 194 and 195 are objected to because of the following informalities:

Claim 192(i) is objected to because of reciting "...fragment of amino acid sequence of SEQ ID NO: 162...," it should be noted that SEQ ID NO: 162 is encoded by a polynucleotide insert of clone bn268_11, which is not claimed here.

Claim 194 is objected to because it depends from a cancelled claim 196.

Claim 195 is objected to because of a spelling error "sais."

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 192, 194 and 195 are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed polynucleotides are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed polynucleotides or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed polynucleotides or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

The specification, on pages 87-89 and 177-178 describes clone bn97_1 to which the instant invention relates. Applicants assert (page 178) that the predicted bn97_1 protein demonstrated at least some similarity to sequences of Hepatitis-B virus surface antigen P31 protein for example. Further the specification indicates that the bn97_1 protein also shows some identity to both bovine and human lectin-like receptor for oxidized low-density lipoprotein (LDL). The alignments have not been provided and no percent similarity is disclosed. The specification at page 177 also indicates bn97_1 cDNA was identified as encoding a secreted or or transmembrane protein.

However, the specification fails to provide any sequence with such region, which is a structural characteristic of a Hepatitis-B virus surface antigen P31 protein or bovine and human lectin-like receptor for oxidized low-density lipoprotein; or provides any activity of the polypeptide, which would be similar to the activity of a P31 protein and/or a lectin-like receptor for oxidized low-density lipoprotein. Therefore, only on the basis of some sequence similarity to P31 protein and/or a lectin-like receptor protein, the protein of clone bn97_1 cannot be identified as a member of P31 protein and/or a lectin-like receptor protein family.

Based on the specification (pages 87-89 and 177-178), no biological activity has been set forth for the polypeptide encoded by polynucleotide of clone bn97_1 nor any use for the polynucleotide itself has been provided. However, speculative biological activities have been provided on pages 210-226 of the specification. For example, the use of the polynucleotide for

further research is described here (page 210). This use is not an acceptable patentable utility because one skilled in the art should not have to discover for themselves the use of the claimed polynucleotides. This situation requires carrying out future research to identify or reasonably confirm a "real world" context of use and therefore do not define specific and substantial utility.

The specification on page 211 states that the polynucleotide and proteins can be used as a nutritional source or supplements. This use is considered to be a " throw away" utility and does not distinguish the claimed polynucleotide over any other polunucleotide. The utility is not specific or substantial.

Other activities that the protein encoded by the polynucleotide may exhibit are listed throughout pages 226-232 of the specification. However, these activities are purely speculative. In summary, the polynucleotides claimed do not have a credible, specific or well-established utility and therefore lacks utility under 35 U.S.C. 101.

Claim 192 (h, i), is drawn to a polynucleotide encoding a protein comprising amino acid sequence of SEQ ID NO: 160 and a fragment thereof. The specification does not describe the functional properties of the protein and its fragments, and the structural information is limited. While the specification enumerates several known assays for biological activity (pp. 212-213), it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed fragments.

Claim 192 (d, e) is directed to polynucleotides encoding full-length proteins of clone bn97_1. It is not clear from the description of the clone (specification pages 87-89 and 177-178) about the protein structure, aside from its full-length amino acid sequence, and/or its function.

Claim 192 (a, b, c, l) are directed to polynucleotides comprising the sequence of SEQ ID NO: 159 and fragments thereof. As discussed above, based on the specification (pages 87-89 and 177-178) it is unclear what activity the claimed polynucleotides possess, what activity the encoded proteins possess and therefore unclear how a person having skill in the art might use the claimed polynucleotides. It would require undue experimentation for a person having skill in the art to be able to use the claimed polynucleotides. It is *a priori* unpredictable based on the instant

disclosure what activity the claimed polynucleotides possess because no correlation has been made between the claimed polynucleotides and a specific activity.

In the instant case, the failure of applicants to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the polynucleotides of SEQ ID NO: 159 or encoding the protein set forth in SEQ ID NO: 160 other than the fact that the protein may be secreted (p. 177). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 160 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 192, 194 and 195 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claim 192 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim 192 embraces species homologues and allelic variants.

Claim 192 (k) is drawn to a polynucleotide, which encodes a species homologue of the protein of (h) or (i) of claim 192. There is no guidance about what percent identity the two encoding genes must have, no specific probe/primer and specific hybridization of PCR conditions, which can be used so that one would reasonably expect the DNA obtained under those specific conditions is a species homologue. The specification provides insufficient guidance to allow one skilled in the art to obtain species homologues because the method to do so presented on page 205, lines 10-14, 21-23 recites only " species homologs may be isolated and identified making suitable probes or primers from the sequences provided herein and screening a suitable nucleic acid source from the desired species." There is no information about how to identify a "suitable" probe or primer. Additionally, species homologues often display low sequence identity so that identification based solely on sequence similarity is unpredictable. Under such common circumstances, if one cannot test for an expected activity of the encoded putative species homologue, then it is impossible to confirm existence of species homologues. Neither sufficient structural guideline to reliable identify species homologues nor a specific function which could be used to confirm that an isolated nucleic acid was a species homologue of a recited polypeptide is provided in the specification. Further, the term "homologue", if only sequence similarity is used to establish "homology", cannot define a connection of common evolutionary origin. Nucleic acids, which encode proteins that are species homologue, would have a common evolutionary origin. For these reasons, it would require undue experimentation to determine if the compound has biological activity and, therefore, to make and use the claimed invention.

Claim 192(j) directs to an allelic variant of a polynucleotide of (a-g) of claim 192. The specification describes allelic variations as "naturally-occurring alternative forms of the isolated polynucleotide which also encode proteins which are identical or have significantly similar sequences to those encoded by the disclosed polynucleotides (description page 206, lines 1-4). According to Ayala et al. (Modern Genetics, Glossary), an allele is "one of two or more

alternative forms of a gene, each possessing a unique nucleotide sequence; different alleles of a given gene are usually recognized, however, by the phenotypes rather than by comparison of their nucleotide sequences." The current description has disclosed no genes, where gene means genomic DNA, comprising the coding sequence of a protein. The sequences, which are disclosed, are those of cDNA. If two cDNAs differ from each other, it is impossible to tell, without the genomic DNA in hand, whether the difference arose because of an allelic variation, transcriptional modification going from genomic DNA to mRNA, post transcriptional processing of RNA, or an error in reverse transcription of mRNA into cDNA. The nature of allelic variation makes it entirely unpredictable what might be considered an allele before the isolation of such a sequence has actually taken place. The specification does not describe what might be considered an allele of the DNA of section (a-j) of claim 192 or provide any examples of the same. Since the disclosed cDNA encoding a polypeptide has not been ascribed a specific function, it does not appear that allelic variants have been isolated or identified. There are no examples of allelic sequences of the claimed DNA to which one could compare undisclosed DNA to determine if they are also alleles. For these reasons the claimed allelic variants have not been adequately described, and a person having ordinary skill in art would not recognize a specific utility for the polynucleotide and would not know how to use them.

Also, if you don't know what an allelic variant or homologue looks like, what then does a hybridized polynucleotide look like. Therefore, polynucleotides that hybridize to the allelic variants or homologues that are not described cannot be envisioned by the teachings of the specification.

Claim 192 (l) is directed to a polynucleotide sequence that hybridizes to the polynucleotides of section (a-i) of claim 192. Applicants have not sufficiently defined the specific conditions of stringency under which the hybridization is to take place. Although several stringent conditions: highly stringent, stringent and reduced stringent conditions are listed in the table given on the page 206-207 of the specification.

For these reasons, it would require undue experimentation to make the claim invention.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 192, 194 and 195 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 192 is indefinite because it is not clear from the claim or the specification how in claim 192 (l), that the polynucleotide that must hybridize to the polynucleotide of items (a-i) of claim 192 encodes the same protein. In one instance, the polynucleotide is the coding strand and in the other it is the non-coding strand. If the coding strand contains 5' ATG (encodes Met), the non-coding strand is 5' CAT (encodes His). Claim 192 (l) also refers to "stringent conditions," however; both the specification and the art lack an unambiguous definition of that term. The specification (page 206) describes highly stringent, stringent and reduced stringent conditions, however without defining stringent conditions the claim remains indefinite on the basis of absence of definition of "stringent conditions". This rejection can be overcome by including in the claim the specific stringent condition. Claims 194 and 195 are included in the rejection because the claims are dependent on rejected claim 192 and do not correct the deficiency from the claim from which they depend.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 192, 194 and 195 are rejected under 35 USC 102 (b) as being anticipated by Jacobs et al. (WO 99/13066, March 18, 1999).

Jacobs et al. teach a cDNA clone bn97_1 codes for a human secreted protein from human adult placenta, adult testes and foetal brain cDNA libraries, wherein the secreted protein nucleic acid sequences correspond to clone bn97_1 having 100% nucleic acid sequence identity to SEQ ID NO: 159 (nucleotides 1-1776), (see alignment result 1, Database: N_Geneseq_16Dec04, Accession NO: AAX33810). The reference also teaches a polynucleotide encoding the amino acid sequence that has 100% amino acid sequence identity to SEQ ID NO: 160, (see Frame search alignment result 3, Database: N_Geneseq_16Dec04, Accession NO: AAX33810). Jacob's cDNA insert length is 1776 bp, that encodes a protein having 280 amino acids of SEQ ID NO: 160, therefore this sequence is considered for hybridizing to the polynucleotide of SEQ ID NO: 159 that encodes a protein of SEQ ID NO: 160 (claim 192). Jacob's clone bn97_1 is deposited in composite clone ATCC 98535, thus Jacob et al. anticipate claim 192 of the instant application (see summary, and page 19-20 of WO ref). Jacobs' polynucleotide sequence is considered for hybridizing to the polynucleotide of SEQ ID NO: 159 of claim 192 (a-i); and polypeptide sequence is considered for a protein of SEQ ID NO: 160; and thus anticipates claim 192 of instant application.

Jacobs' cDNA is inserted in vector pMT2 or pED (see page 35, lines 18-21 of WO ref), and expressed in mammalian host cells (see page 35, lines 28-33 of WO ref) thus anticipating claims 194 and 195 of instant application.

Conclusions

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm. If attempts to reach the examiner

by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

Rita Mitra, Ph.D.
October 11, 2005